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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/035,708	03/05/1998	FRANK P. ZEMLAN	91830	5121

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EXAMINER

HAYES, ROBERT CLINTON

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 11/18/2003

45

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/035,708

Applicant(s)
Zemlan et al

Examiner
Robert C. Hayes, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Aug 4, 2003
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14, 17, 19, 21-24, 26, 27, 29, 32, and 33 is/are pending in the application.
- 4a) Of the above, claim(s) 1-13, 21, and 22 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 32 is/are allowed.
- 6) ☒ Claim(s) 14, 17, 19, 23, 24, 26, 27, 29, and 33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-14, 17, 19, 21-24, 26, 27, 29, 32, and 33 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/04/03 has been entered.

2. The amendment filed 8/04/03 has been entered.

3. The oath or declaration remains defective, for the reasons made of record in Paper Nos: 17 (mailed 8/16/00), 25 (mailed 7/23/01) and 28 (mailed 1/02/02). A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because it remains unsigned.

4. The rejection of claims 14, 17, 19-20, 23-24, 26-27, 29 & 32-33 under 35 U.S.C. 112, first paragraph, for new matter is withdrawn due to either the cancellation or amendment of the claims to reflect those injuries described on pages 4 and 5 of the specification.

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5. The rejection of claim 20 under 35 U.S.C. § 112, second paragraph, as being indefinite for the recitation of "said... tau protein lacks the native N-terminal and C-terminal amino acids" is withdrawn due to the cancellation of this claim.

6. Claim 32 is allowed.

7. Applicants' arguments filed 8/04/03 have been considered but are not found persuasive.

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

9. Claims 14, 17, 19, 23-24, 26-27, 29 & 33 stand rejected under 35 U.S.C. 102(b) as being anticipated by Vandermeeren et al (WO 94/13795), for the reasons made of record in Paper NOs: 12 (mailed 1/24/00), 17 (mailed 8/16/00), 25 (mailed 7/23/01), 28 (mailed 1/02/02) & 35 (mailed 8/16/02), and as follows.

Applicants argue on pages 6-7 of the response that claim 14, etc. recites "acute conditions", which do not include Alzheimer's disease, as taught by Vandermeeren et al., and then cites *3M Unitech Corp. V. Ormco Co.* In contrast to Applicants' assertions, Alzheimer's disease is reasonably a "primary neurological injury" that may include "secondary traumatic lesions", as claimed, for the reasons extensively made of record; especially when taken in context

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with that disclosed on page 4 (line 17) through page 5 (line 4) of the specification, which specifically lists Alzheimer's disease as a "CNS injury"/neurological trauma. In addition, as previously made of record, "primary neurological injuries..., or secondary traumatic lesions" reasonably include those neurological traumas affected during Alzheimer's disease, because the central nervous system basal forebrain cholinergic neurons are affected/injured/die during Alzheimer's disease (i.e., "primary" or "secondary" neurological events), in which the broad and generic recitation of "neurologic trauma selected from... primary neurological injuries..., or secondary traumatic lesions" encompasses all injured CNS neurons (e.g., see pages 4-5 of the specification), including those affected during Alzheimer's disease (i.e., especially as it relates to "secondary traumatic lesions", as also argued in the Broderick 12/17/02 Declaration). In other words, Applicants' argument that the claims are now limited to "acute conditions" is incorrect. Thus, Applicants' arguments remain not persuasive for the reasons made of record.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (703) 305-3132. The examiner can normally be reached on Monday through Thursday, and alternate Fridays, from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Robert C. Hayes, Ph.D.
November 14, 2003

